



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 16 2007

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

In re Application of :
Joerg Schneider et al. :
Serial No.: 10/088,677 : PETITION DECISION
Filed: May 31, 2002 :
Attorney Docket No.: 620-190 :

This is in response to the petition under 37 CFR 1.144, filed July 31, 2006, requesting withdrawal of an improper restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application is a national stage filing under 35 USC 371 of PCT/GB00/03601 and as such, is eligible for PCT unity of invention practice.

The examiner mailed to applicants on May 31, 2006, a lack of unity determination, wherein claims 9-16 were divided into three groups which lacked unity in view of Kazanji et al. The examiner reasoned that Kazanji et al. taught the shared technical feature of boosting a CD8+ T cell immune response to an antigen by administering a boosting composition comprising a replication-deficient adenoviral vector including nucleic acid encoding said antigen or epitope operably linked to regulatory sequences. The claims were restricted as follows:

- I. Claims 9 and 14-16, drawn to a method of boosting a CD8+ T cell immune response to an antigen in an individual, wherein said individual is previously primed with a non-adenoviral vector.
- II. Claims 10, 12 and 13, drawn to a method of inducing CD8+ T cell immune response, comprising administering to the individual a priming composition comprising the antigen or a CD8+ T cell epitope of said antigen.
- III. Claims 10-13, drawn to a method of inducing a CD8+ T cell immune response, comprising administering to the individual a priming composition comprising nucleic acid encoding the antigen or a CD8+ T cell epitope of said antigen.

Applicants replied on January 18, 2005, electing Group III (claims 10-13), with traverse. Applicants argued that all three groups of inventions refer to administration of a replication-

deficient adenoviral vector encoding an antigen, to boost an immune response to the antigen in an individual, where the individual was previously primed with a heterologous composition (heterologous prime-boost). Applicants further argued that Kazanji et al. does not teach heterologous prime-boost.

The examiner mailed a new Office action on March 21, 2006, acknowledging the election of Group III and the traversal. The examiner maintained the lack of unity and made the lack of unity determination Final. Claims 9 and 14-16 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 10-11 and 18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/686,943. Claims 10-13 and 17-21 were rejected under 35 USC 112, second paragraph, and under 35 USC 103(a).

Applicants filed a response to the non-final Office action along with this petition on July 31, 2006, asking review of the lack of unity determination.

DISCUSSION

Applicants request rejoinder of Group II (method of priming with the antigen) with Group III (method of priming with a nucleic acid encoding the antigen). However, applicants have amended the claim set such that there are no claims pending which are directed to Group II.

Applicants have also requested rejoinder of Group I with Group III.

The lack of unity determination has been made between Group I, claims 9 and 14-16 and Group III, claims 10-13, which are currently under examination. Independent claims 9 and II are shown below as representative of Group I and II, respectively.

9. (Withdrawn) A method of boosting a CD8+ T cell immune response to an antigen in an individual, the method including provision in the individual of a replication-deficient adenoviral vector including nucleic acid encoding the antigen or a CD8+ T cell epitope of said antigen operable linked to regulatory sequences for production of said antigen or epitope in the individual by expression from the nucleic acid, whereby a CD8+ T cell immune response to the antigen previously primed with a non-adenoviral vector in the individual is boosted.

10. (Currently amended) A method of inducing a CD8+ T cell immune response to an antigen in an individual, the method comprising administering to the individual a priming composition comprising nucleic acid encoding said antigen or a CD8+ T cell epitope of said antigen and then administering a heterologous boosting composition which comprises a replication-deficient adenoviral vector including nucleic acid encoding said antigen or epitope operably linked to regulatory sequences whereby said antigen or epitope is expressed in the individual.

The petition argues that with the amendment of claim 10, both groups are directed to "administration of a replication-deficient adenoviral vector encoding an antigen, to boost an

immune response to the antigen in an individual, where the individual was previously primed with a heterologous composition." See paragraph bridging pages 2-3 in the petition.

Applicants contend the Kazanji et al. either used 1) an Ad5-HTLV-1-env for priming and an Ad5-HTLV-1-gp46 or recombinant gp46 protein for boosting or 2) the naked DNA expression vector pMLP-HTLV-1-env for priming and a naked DNA expression vector pMLP-HTLV-1-gp46 or recombinant gp46 protein for boosting (page 301, Tables 1A and 1B). Thus, Kazanji et al. discloses using adenovirus in a homologous prime-boost context when adenovirus is used as a boosting composition.

Applicants argue that Kazanji et al. do not teach "heterologous prime-boost" as instantly required. McMichael (WO 98/56919) teaches boosting compositions comprising pox-virus vectors and that MVA can be used in both priming and boosting compositions. See the rejection made under 35 USC 103(a) in the previous Office action. For this combination of references, the shared technical feature does not make a contribution over the prior art.

DECISION

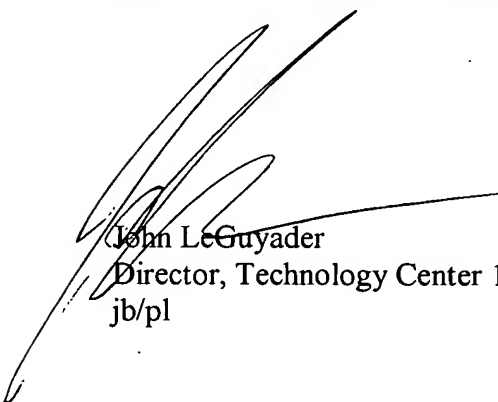
The petition is **DENIED** for the reasons set forth above. The lack of unity determination made between Groups I and III has been maintained.

The request to rejoin Group II with Group III is dismissed because there are no claims pending which are directed to Group II.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to consider the papers filed 31 July 2006.

Should there be any questions about this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.



John LeGuyader
Director, Technology Center 1600
jb/pl